

ACCOMPANYING LABELING: Leaflet entitled "Dorsey Tain[®] Composition" and folder entitled "Time to Take 'Em Out Again."

RESULTS OF INVESTIGATION: New drug applications for these articles were made effective with labeling offering them specifically for the "symptomatic relief of the common cold (malaise, headache, muscular cramps, aches and pains) and the prevention of secondary complications due to susceptible organisms" and with the caution that "if resistant infection or super infection appears discontinue the drug and institute specific therapy or supportive treatment," whereas the article was being recommended and suggested for the treatment of susceptible infections which complicate the common cold, other respiratory infections and other infections.

LIBELED: On or about 2-13-62, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective as a treatment for tonsillitis, pharyngitis, otitis media, bronchitis, pneumonitis, bronchopneumonia, rhinitis, cervical lymphadenitis, coryza, lobar pneumonia, tracheitis or tracheobronchitis, influenza, adenoiditis, bronchial asthma, croup and postnasal infection; that the analgesic ingredient, namely, acetaminophen, was safer in children than salicylates; that the antipyretic effect of the articles did not mask the diagnostic importance of persistent fever; and (*Tain oral suspension*) that it met pediatric requirements in upper respiratory infections; that when side effects occur they were not usually attributable to the article; that the article was an upper respiratory infections antibiotic proved effective in pediatric use; that it was indicated in the treatment of susceptible infections which complicate the common cold, and other respiratory infections; that children did not become drowsy from antihistamines; 502(f) (1)—the labeling failed to bear adequate directions for use and the articles were not exempt from the requirement, since the promotional material for the articles was not the same as, or substantially the same as, the labeling authorized by the new drug applications filed with respect to the articles; and 505(a)—the articles were new drugs, and the new drug applications filed with respect to the articles did not apply to the conditions for which the articles were promoted to the medical profession as set forth in statements contained in the promotional material.

DISPOSITION: 4-24-62. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR HUMAN USE

7005. Streptomycin-procaine penicillin. (F.D.C. No. 47744. S. No. 32-899 T.)

QUANTITY: 448 vials at Los Angeles, Calif.

SHIPPED: During 1960, from New York, N.Y.

LABEL IN PART: "Control: 7G50 10 cc. Streptomycin-Procaine Penicillin Aqueous Suspension Procaine Penicillin 400,000 Units Streptomycin 0.5 Gm. Base per 2 cc."

RESULTS OF INVESTIGATION: Assay showed no significant penicillin potency in the article.

LIBELED: 6-11-62, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(1)—the article was a drug composed in part of penicillin and it was from a batch with respect to which a certificate issued pursuant to 507 had ceased to be effective by reason of its penicillin potency.

DISPOSITION: 7-31-62. Default—destruction.

DRUG FOR VETERINARY USE

7006. Medicated feed. (F.D.C. No. 46754. S. No. 34-802 T.)

QUANTITY: 25 cases, 6 3½-lb. cans each, at Mankato, Minn., in possession of Paul's Products Co.

SHIPPED: 11-23-60, from Indianapolis, Ind.

LABEL IN PART: (Can) "Paul's 3½ Pounds * * * Mycine—4 Water Dispersible Antibiotic Vitamins Each Pound Contains Procaine Penicillin 4 Grams * * * Vitamin K (Menadione Sodium Bisulfite) 120 Mgms. * * * Manufactured by Paul's Products Co. Mankato, Minnesota."

RESULTS OF INVESTIGATION: The article was manufactured in part from raw material (procaine penicillin G), which was shipped on the above date.

LIBELED: 12-29-61, Dist. Minn.

CHARGE: 502(1)—while held for sale, the article contained procaine penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507, and it was not exempt from the requirements of certification.

DISPOSITION: 3-6-62. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

7007. Various prescription drugs. (F.D.C. No. 46452. S. Nos. 729/31 T, 734 T, 736/9 T, 741/2 T.)

QUANTITY: 12,426 tablets and capsules, 172 btls. of liquids, and 35 tubes, jars, and cans, at Charleston, S.C., in possession of Prescription Center, Inc.

SHIPPED: On unknown dates, by various drug handlers.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked from physicians' samples into bottles and other containers to which had been affixed labels (in most cases the label originally affixed to the physicians' sample container) bearing the brand names of the drugs, a "complimentary-not for sale" professional sample legend, and the name and address of the manufacturers, packers, or distributors located outside the State of South Carolina; and some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs and bearing labels containing a "complimentary-not for sale" professional sample legend, and the name and address of the manufacturer, packer, or distributor located outside the State of South Carolina.

LIBELED: 9-16-61, E. Dist. S.C.

CHARGE: 502(a)—while held for sale, the words "Professional Sample," "Sample-Not To Be Sold," "Physician's Sample," "Physician's Package," and similar wording on the labels of some of the articles, were false and misleading as applied to these articles in the possession of a repacker and intended for sale